

### **REMARKS**

Claims 1, 3, 6-7, 17, 20-22, 27, 29, 30, 32-36, 42-44, 47-49, 63, 64, 66-73, 78, 81-83, 92, and 93 constitute the pending claims in the present application. Applicants cancel, without prejudice, previously withdrawn claims 4, 5, 18, 19, 24, 25, and 85-91. Applicants additionally cancel, without prejudice, claims 6, 20, 21, 22, 33, 64, 70-73, 81-83, and 93. Applicants add new claims 94-97. Support for the subject matter of these claims is found throughout the specification. No new matter has been entered. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note with appreciation that the previously filed amendments have been entered.

2. Applicants' amendment to the specification to correct the typographical error in the title is believed to obviate any objection.

3. Applicants note that the objection to claims 34, 47-49, and 68-69 has been withdrawn.

Claim 6 is objected to for allegedly failing to further limit the subject matter of the previous claim. As indicated by the Examiner, claim 6 and 17 are directed to subject matter of the same scope. Accordingly, Applicants hereby cancel claim 6, thereby rendering the objection moot. Reconsideration and withdrawal of this objection is requested.

4. Claims 6, 17, 20-22, 27, 29-30, 32-36, 42-44, 47-49, 63-64, 66-73, 78, 81-83, and 92-93 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. These claims are further rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to satisfy the enablement requirement. Applicants traverse these rejections and contend that the rejections are moot in light of the amended claims.

Applicants reiterate the arguments of record and contend that the specification provides ample support for the claimed subject matter. Nevertheless, to expedite prosecution of claims directed to certain embodiments of the invention, Applicants have amended the claims to more particularly point out that signaling via the hedgehog pathway is evaluated by detecting a change

in *GLI* expression in the cell. Specifically, Applicants have amended claims 17, 30, 63, 78, and 92 and have canceled claims 6, 20, 21, 22, 33, 64, 70-73, 81-83, and 93. Support for the claimed subject matter is found throughout the specification, for example, on page 64, lines 3-35. The claimed subject matter is supported by the specification and one of skill in the art is enabled to practice the claimed invention throughout its scope.

Applicants note that Applicants' cancellation of and amendments to the claims are believed to obviate the rejection. However, Applicants note for the record that cancellation of and amendments to the claims are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of these rejections are respectfully requested.

5. Claims 78 and 81-83 are rejected under 35 U.S.C. 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants contend that claims 78 and 81-83 are clear, and that one of skill in the art would readily appreciate the metes and bounds of the claimed subject matter. Nevertheless, to expedite prosecution, Applicants have amended claim 78 to incorporate the Examiner's suggestion. Specifically, as suggested by the Examiner at page 7 of the Office Action, Applicants have amended the preamble of claim 78 to read "... agents that antagonize the hedgehog pathway." Applicants' amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope.

As outlined in section 4 above, Applicants have cancelled dependent claims 81-83. Applicants' cancellation of claims 81-83 renders rejection of those claims moot.

For the reasons presented above, Applicants submit that the pending claims are fully compliant with 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

6. Applicants note with appreciation that the rejection under 35 U.S.C. 102(e) has been withdrawn.

7. Applicants note with appreciation that the Examiner has indicated that claims 1, 3, and 7 are in condition for allowance.

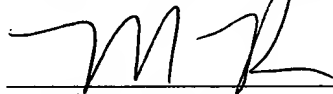
### CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. HMSU-P14-006.**

Date: February 14, 2005

**Customer No: 28120**  
Docketing Specialist  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050

Respectfully Submitted,



---

Melissa S. Rones  
Reg. No. 54,408